REMARKS

Prosecution

Applicants respectfully request reconsideration of the outstanding rejections in view of Applicants' instant claim amendments and the following Remarks.

Specification Amendments

The amendment made herein is to insert the priority claim into the specification. Applicants note that the USPTO requires that the claim of priority to another application be set forth in the first sentence(s) of the specification following the title, preferably as a separate paragraph, pursuant to 37 C.F.R. § 1.78(a) and/or in an application data sheet (ADS) pursuant to 37 C.F.R. § 1.76. Applicant submits that no petition or fee is required for entry of this amendment as prescribed in M.P.E.P. § 201.11. Applicants respectfully request entry of the amendment and submit that the amendment does not constitute new matter.

Claim Amendments

Upon entry of the foregoing amendment, claims 3-6, 8-10, 14, 17-18, and 21-36 are pending in the application. Claims 3-6, 8-10, 14, and 17-18 have been amended. Claims 21-36 are presented for entry and consideration. Claims 11-13, 15-16, and 19-20 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue the Canceled subject matter in one or more divisional and/or continuation applications. Support for the new claims and claim amendments can be found throughout the specification and in the claims as originally filed, for example, at page 5, lines 5-10; page 8, lines 8-12; page 10, lines 12-14; and page 19, lines 3-7. Applicants respectfully request entry of the amendments and new claims and submit that the amendments and new claims do not constitute new matter.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 11 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 11 has been Canceled rendering this rejection *moot*.

Rejections under 35 U.S.C. § 102

Claims 3-6 and 8-20 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by UK Patent Application GB 2 180 539 ("GB '539"). Applicants respectfully traverse this rejection.

Applicants have amended claims 3-6, 8-10, 14, and 17-18 and Canceled claims 11-13, 15-16, and 19-20. To the extent that the rejection pertains to the amended claims, Applicants make the following remarks.

Independent claims 9, 10, 17, 18, 33, and 35 variously require that the formation of byproduct polypeptide is reduced in an amount greater than or equal to 50% as compared to a control medium with no methionine, histidine, or glycine added. Applicants submit that GB '539 does not teach this limitation.

The Office Action cites GB '539 which uses yeast extract in a culture medium. See GB '539 at 10, lines 26-29. However, GB '539 is silent on the composition of the yeast extract, the supplier of the yeast extract, and the presence and amount of methionine, histidine, and glycine present in the culture medium. The Office Action cites an unrelated reference, Manual of BBL® Products and Laboratory Procedures ("Manual") to support the supposition that, "...yeast extract is composed of different amino acids." Office Action at 3. The Manual, however, fails to specify if the amount of methionine, histidine, and glycine present is an amount effective to reduce byproduct formation, as required by the claims.

Applicants respectfully submit that to establish inherency by the use of extrinsic evidence, this evidence

> must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) [*internal citations omitted*].

To the extent that the Examiner is relying on inherency, Applicants submit that neither the GB '539 nor the Manual make clear that the missing descriptive matter is necessarily present in the references, namely, that the amount of methionine, histidine, and glycine is present in an amount effective to reduce byproduct formation as required by the claims.

Finally, claims 14, 26, 34, and 36 recite that 3.0 g/L of methionine are used in the method, an amount not taught by GB '539 or reasonably inferred from the cited Manual.

Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 3-6 and 8-20 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent Application Publication No. 2003/0170811 (September 11, 2003) Ueda, *et al.* ("the '811 publication"). Applicants respectfully traverse this rejection.

Applicants have amended claims 3-6, 8-10, 14, and 17-18 and Canceled claims 11-13, 15-16, and 19-20. To the extent that the rejection pertains to the amended claims, Applicants make the following remarks.

Independent claims 9, 10, 17, 18, 33, and 35 variously require that the formation of byproduct polypeptide is reduced in an amount greater than or equal to 50% as compared to a control medium with no methionine, histidine, or glycine added. Applicants submit that the '811 publication does not teach this limitation.

The Office Action cites the '811 publication which uses L-broth in a culture medium. See '811 publication at Example 14. However, the '811 publication is silent on the composition and supplier of the yeast extract in the L-broth, and the presence and amount of methionine, histidine, and glycine present in the L-broth. The Office Action cites an unrelated reference, Handbook of Microbiological Media ("Handbook") to support the supposition that, "the L-broth...contains yeast extract, which is composed of different amino acids." Office Action at 4. The Handbook, however, fails to specify the amount of methionine, histidine, and glycine present in the L-broth and if this is an amount effective to reduce byproduct formation, as required by the claims.

Applicants respectfully submit that to establish inherency by the use of extrinsic evidence, this evidence

> must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) [*internal citations omitted*].

To the extent that the Examiner is relying on inherency, Applicants submit that neither the '811 publication nor the Handbook make clear that the missing descriptive matter is necessarily present in the references, namely, that the amount of methionine, histidine, and glycine is present in an amount effective to reduce said byproduct formation as required by the claims.

Finally, claims 14, 26, 34, and 36 recite that 3.0 g/L of methionine are used in the method, an amount not taught by the '811 publication or reasonably inferred from the cited Handbook.

Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 3-6 and 9-14 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,670,340 (September 23, 1997) Yabuta, *et al.* ("the '340 patent"). Applicants respectfully traverse this rejection.

Applicants have amended claims 3-6 and 9-10 and Canceled claims 11-13. In particular, Applicants have amended claims 9 and 10 to include the limitation of claim 16. To the extent that the rejection pertains to the claims as instantly presented, Applicants make the following remarks.

Independent claims 9 and 10 require that the method include a step of adding methionine and at least one of histidine or glycine to the medium in an amount effective to reduce byproduct formation and that the formation of byproduct polypeptide is reduced in an amount greater than or equal to 50% as compared to compared to a control medium with no methionine, histidine, or glycine added. Claim 14 recites that 3.0 g/L of methionine is used in the method of claims 9 and 10. Applicants submit that the '340 patent does not teach or suggest these limitations.

Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Applicants respectfully submit that claims 3-6, 8-10, 14, 17-18, and 21-36 are in condition for allowance, and such disposition is earnestly solicited. Should the Examiner believe that any patentability issues remain after consideration of this Response, the Examiner is invited to contact the Applicants' undersigned representative to discuss and resolve such issues.

In the event that a variance exists between the amount tendered and that deemed necessary by the U.S. Patent and Trademark Office to enter and consider this Response or to maintain the present application pending, please credit or charge such variance to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,

Dated: June 26, 2007

By: _____

Robert M. Schulman
Registration No. 31,196

Christopher J. Nichols, Ph.D.
Registration No. 55,984

HUNTON & WILLIAMS LLP
Intellectual Property Department
1900 K Street, N.W. Suite 1200
Washington, DC 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

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